UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF TEXAS

IN RE: DEPUY ORTHOPAEDICS INC, PINNACLE HIP IMPLANT PRODUCTS LIABILITY LITGATION	**MDL DOCKET NO. 3:11-2244**
Plaintiff JUDITH M. SPARANGES, by and through her attorneys, WEITZ & LUXENBERG, P.C., vs. DEPUY ORTHOPAEDICS, INC.; DEPUY, INC.; JOHNSON & JOHNSON; JOHNSON & JOHNSON SERVICES, INC.; JOHNSON & JOHNSON INTERNATIONAL, Defendants. _____	§ § **CIVIL ACTION NO. _____** § § **JUDGE ED KINKEADE** § § § **COMPLAINT and DEMAND FOR JURY TRIAL** § § § § §

COMPLAINT FOR DAMAGES

The injured Plaintiff(s) JUDITH M. SPARANGES, by and through her attorneys, WEITZ & LUXENBERG, P.C., ("the injured Plaintiff"), allege on information and belief against DEPUY ORTHOPAEDICS, INC., DEPUY, INC.; JOHNSON & JOHNSON; JOHNSON & JOHNSON SERVICES, INC., JOHNSON & JOHNSON INTERNATIONAL, ("Defendants"), the following:

I.

INTRODUCTION AND SUMMARY OF ACTION

1. Defendants manufactured the Pinnacle Acetabular Cup System ("Pinnacle Device"), and launched it in 2001. The Pinnacle Device was designed, developed, and sold for human hip joints damaged or diseased due to fracture, osteoarthritis, rheumatoid arthritis, and avascular necrosis. The Pinnacle Device was designed and sold to provide pain relief and consistent and smooth range of motion. Defendants marketed the Pinnacle Device as having significant advantages over other hip devices and hip replacement systems. Defendants marketed and described the Pinnacle Device as "[u]niquely designed to meet the demands of active patients like you –and help reduce pain" and advertised it with pictures of a young woman trying on sneakers in an athletic shoe store. Defendants advertised the Pinnacle Device as a superior device featuring TrueGlide technology, allowing the body to create a thin film of lubrication between surfaces, which enables "a more fluid range of natural motion."

2. Defendants also advertised and sold the Pinnacle Device as the best surgical option that "[r]ecreates the natural ball-and-socket joint of your hip, increasing stability and range of motion."

3. On information and belief, the injured Plaintiff alleges that Defendants sold approximately 150,000 Pinnacle Devices. Defendants have stated in promotional materials that "99.9% of Pinnacle Hip components are still in use today."

4. On information and belief, the injured Plaintiff alleges that over 1,300 adverse reports have been submitted to the U.S. Food and Drug Administration (FDA) regarding failures or complications of the Pinnacle Device.

5. On information and belief, the injured Plaintiff alleges that Defendants are aware that the use of the Pinnacle Device may result in metallosis, biologic toxicity, and a high failure rate. The injured Plaintiff further alleges that use of the Pinnacle Device results in unsafe release of toxic metal ions into hip implant recipients' tissue and bloodstream. The injured Plaintiff further alleges that Defendants are aware that metal particles from the Pinnacle Device results in metallosis, tissue death, bone erosion, and development of tumors.

6. Literature relating to Pinnacle Hips demonstrates that since at least 2006 DePuy was on notice of design problems showing that the Pinnacle metal-on-metal hip implant, like DePuy's ASR Hip, have a propensity to deform which can result in edge loading and loosening, and to cause increased wear and hence metal ion dispersion.

7. An article published in September 2006, in the Journal of Arthroplasty, found that the stiffness of the Pinnacle cup lead to an exceptionally high rate of acetabular component deformation secondary to insertion, potentially caused by the press-fit technique. This study reported that an astounding "90.5% of [Pinnacle] cups had measurable compression deformity, averaging 0.16 +/- 0.16 mm. The corresponding forces acting on these cups averaged 414 +/- 421 N. For hard-on-hard bearing surfaces, such in vivo deformation of acetabular shells may result in negative clinical consequences such as equatorial loading with increased wear and potential seizing of components, chipping of ceramic inserts, or locking mechanism damage."

8. Another study published in December 2010, in the Journal of Orthopaedic and Trauma Surgery reported that for patients implanted with metal-on-metal Pinnacle Hips (36-mm femoral head), serum levels of cobalt and chromium were found to be significantly increased at three (3) months postoperatively, compared to preoperative levels.

9. On information and belief, the injured Plaintiff alleges that particulate debris from the Pinnacle Device causes severe inflammation, severe pain, tissue and bone loss, and other related diseases.

10. The injured Plaintiff further alleges that Defendants are aware that certain Pinnacle Device recipients have elevated cobalt and chromium levels greatly exceeding acceptable safety standards.

II.

PARTIES

11. The injured Plaintiff JUDITH M. SPARANGES is, and at all times relevant to this Complaint was, a resident of the city of Shrewsbury, in the state of Massachusetts.

12. Defendant DEPUY ORTHOPAEDICS, INC. is, and at all times relevant to this Complaint was, an Indiana Corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana 46581. Defendant DEPUY ORTHOPAEDICS, INC. is and was at all times relevant herein doing business in and/or having directed its activities at Massachusetts, and specifically this judicial district.

13. Defendant DEPUY, INC. is, and at all times relevant to this Complaint was, an Indiana Corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana 46581. Defendant DEPUY, INC. is and was at all times relevant herein doing business in and/or having directed its activities at Massachusetts, and specifically this judicial district.

14. Defendant JOHNSON & JOHNSON is, and at all times relevant to this Complaint was, a New Jersey Corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant JOHNSON & JOHNSON is

and was at all times relevant herein doing business in and/or having directed its activities at Massachusetts, and specifically this judicial district.

15. Defendant JOHNSON & JOHNSON SERVICES, INC. is, and at all times relevant to this Complaint was, a New Jersey Corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant JOHNSON & JOHNSON SERVICES, INC. is and was at all times relevant herein doing business in and/or having directed its activities at Massachusetts, and specifically this judicial district.

16. Defendant JOHNSON & JOHNSON INTERNATIONAL. is, and at all times relevant to this Complaint was, a New Jersey Corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant JOHNSON & JOHNSON INTERNATIONAL is and was at all times relevant herein doing business in and/or having directed its activities at Massachusetts, and specifically this judicial district.

17. At all times relevant herein, Defendants, transacted, solicited, and conducted business in the State of Massachusetts, in particular, and derived substantial revenue from such business.

18. At all times relevant herein, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, advertising, promoting, marketing, distributing, labeling, and/or selling the subject product.

19. At all times relevant herein, Defendants expected or should have expected that its acts would have consequences within the United States, and in Massachusetts, in particular.

20. At all times relevant herein, Defendants were the agents of each other, and in doing the things alleged herein, each defendant was acting within the course and scope of its agency and was subject to and under the supervision of its co-defendants.

III.

JURISDICTION AND VENUE

21. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1332(a) because the injured Plaintiff and Defendants are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

22. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a) and (c).

IV.

FACTUAL ALLEGATIONS

A. The Pinnacle Device With An "Ultamet" Liner and/or Pinnacle Metal Insert

23. The Pinnacle Device was developed for the purpose of reconstructing diseased human hip joints from conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis (AVN), fracture, and other degenerative conditions. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is like a ball that fits in a socket. The socket portion of the hip is called the acetabulum. The femoral head at the top of the femur bone rotates within the curved surface of the acetabulum.

24. The Pinnacle Device is made up of four components: the metal femoral stem is inserted inside the femur bone, the metal femoral head (or ball) connects to the top of the stem and then makes contact with a liner that is attached to the interior portion of the metal acetabulum cup (socket). The acetabulum cup is comprised of titanium metal. Either a plastic, ceramic, or cobalt-chromium metal liner is then placed on the inside of the acetabulum cup. The metal femoral head rotates within the plastic, ceramic, or metal liner, depending on which liner the surgeon selects based on the patient's needs. The cobalt-chromium metal liner is branded by Defendants as the "Ultamet" and/or the Pinnacle metal insert. The Pinnacle Device

with an Ultamet liner and/or a Pinnacle metal insert is a "metal-on-metal" device due to the fact that both articulating surfaces – the femoral head (ball) and acetabulum liner (socket) – are comprised of cobalt-chromium metal.

B. Defendants Did Not Seek Premarket Approval From The FDA, And Thus The FDA Made No Finding That The Pinnacle Device Is Safe Or Effective

25. The Pinnacle Device is a Class III medical device. Class III devices are those that operate to sustain human life, are of substantial importance in preventing impairment of human health, or pose potentially unreasonable risks to patients.

26. The Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA"), in theory, require Class III medical devices, including the Pinnacle Device, to undergo premarket approval by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and to submit the results of that investigation to the FDA.

27. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling.

28. The FDA may grant premarket approval only if it finds that there is reasonable assurance that the medical device is safe and effective and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

29. A medical device on the market prior to the effective date of the MDA – a so-called "grandfathered" device – was not required to undergo premarket approval. In addition, a medical device marketed after the MDA's effective date may bypass the rigorous premarket approval process if the device is "substantially equivalent" to a "grandfathered" pre-MDA device (i.e., a device approved prior to May 28, 1976). This exception to premarket approval is known as the "510(k)" process and simply requires the manufacturer to notify the FDA under section 510(k) of the MDA of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then approve the new device for sale in the United States.

30. Rather than being approved for use by the FDA pursuant to the rigorous premarket approval process, the Pinnacle Device metal-on-metal total hip replacement system was certified to be sold on the basis of Defendants' claim that, under section 510(k) of the MDA, it was "substantially equivalent" to another older metal-on-metal hip implant device that Defendants sold and implanted prior to the enactment of the MDA in 1976.

31. As such, under the 510(k) process, Defendants were able to market the Pinnacle Device with virtually no clinical or non-clinical trials or FDA review of the implant for safety and effectiveness.

C. Defendants Took No Steps To Test The Pinnacle Device Or They Would Have Discovered That It Leads To Metallosis And Other Complications Before Releasing It On The Market

32. Had Defendants conducted clinical trials of the Pinnacle Device before it was first released on the market in the early 2000's, they would have discovered at that time what

they ultimately learned in and around 2007 – that the Pinnacle Device results in a high percentage of patients developing metallosis, biologic toxicity and an early and high failure rate due to the release of metal particles in the patient's surrounding tissue when the cobalt-chromium metal femoral head rotates within the cobalt-chromium metal acetabular liner.

33. In other words, implantation of the Pinnacle Device results in the nearly immediate systemic release of high levels of toxic metal cobalt-chromium ions into every hip implant patient's tissue and bloodstream. This is because cobalt-chromium metal particles are released by friction from the metal femoral head rotating within the metal liner. The particles than accumulate in the patient's tissue surrounding the implant giving rise to metallosis, pseudotumors, or other conditions.

34. The formation of metallosis, pseudotumors, and infection and inflammation causes severe pain and discomfort, death of surrounding tissue and bone loss, and a lack of mobility.

35. The problems with the Pinnacle Device are similar to the issues that gave rise to Defendants' recall of their ASR XL Acetabular System and ASR Hip Resurfacing System. Like the Pinnacle Device, the ASR is also prone to early failure, and causes metallosis and cobalt toxicity resulting in serious health problems and the need for subsequent revision surgery. As a result, in August 2010, Defendants, in acknowledging the high failure rate of the ASR, recalled more than 93,000 ASRs worldwide. It is anticipated that Defendants will at some point recall Pinnacle Devices for the same reasons.

36. On information and belief, the injured Plaintiff alleges that the FDA has received more than 1,300 adverse reports regarding problems associated with or attributed to the Pinnacle Device.

37. On information and belief, the injured Plaintiff alleges that many recipients of the Pinnacle Device are suffering from elevated levels of chromium and cobalt. The injured Plaintiff further alleges on information and belief that Defendants are aware that certain recipients of the Pinnacle Device have significantly elevated levels of chromium and cobalt in amounts many times higher than acceptable or recommended safety levels. Notably, the ASR and the Pinnacle Device were designed by the same orthopaedic surgeon, Dr. Thomas Schmalzried.

38. A number of governmental regulatory agencies have recognized the problems that are caused by metal-on-metal implants such as the ASR and Pinnacle Device. For instance, The Medicines and Healthcare Products Regulatory Agency ("MHRA") in Britain investigated Defendants' metal-on-metal total hip replacement system after receiving widespread reports of soft tissue reactions and tumor growth in thousands of patients who had received these implants. MHRA has required physicians to establish a system to closely monitor patients known to have metal-on-metal hips by monitoring the cobalt and chromium ion levels in their blood and to evaluate them for related soft tissue reactions.

39. Similarly, the Alaska Department of Health recently issued a bulletin warning of the toxicity of Defendants' metal-on-metal total hip replacement systems. The State of Alaska, like the MHRA, identified the need for close medical monitoring, surveillance and treatment of all patients who had received these and similar metal-on-metal implants.

40. Despite the public knowledge to the contrary, Defendants' continue to misrepresent the Pinnacle Device as a high-quality, safe and effective hip replacement product in their marketing and promotional materials. This is despite the fact that Defendants have known for years that the Pinnacle Device poses a danger to patients that have it implanted.

41. As a result, Defendants continue to sell the Pinnacle Device to doctors who implant them in countless numbers of patients with an unreasonably high percentage of those patients being forced to endure serious injury from metallosis, pseudotumors, and biologic toxicity, among other complications. These patients are reporting severe pain and discomfort and the need for one or more complicated revision surgeries resulting in life-long health problems caused by the defective device.

D. The Injured Plaintiff Judith M. Sparanges Was Implanted With the Pinnacle Device and As A Result Has Suffered Severe Injuries

42. The injured Plaintiff Judith M. Sparanges was born on June 2, 1955.

43. On or about March 24, 2009, Judith M. Sparanges underwent a surgical procedure to implant a metal-on-metal Pinnacle Device in the right hip at Saint Vincent Hospital.

44. On or about May 19, 2009, Judith M. Sparanges underwent a surgical procedure to implant a metal-on-metal Pinnacle Device in the left hip at Saint Vincent Hospital.

45. As a result of the implanted Pinnacle Devices, the injured Plaintiff experienced debilitating pain, discomfort, and soreness in the area of her hip implants, thereby, negatively affecting her ability to perform activities of daily living.

46. On information and belief, friction and wear between the cobalt-chromium metal head and cobalt-chromium metal liner caused toxic cobalt-chromium metal ions and particles to be released into the injured Plaintiff's blood, tissue and bone surrounding the implants.

47. Laboratory tests have confirmed that the injured Plaintiff has elevated cobalt and chromium levels in the blood that are trending upwards as a result of the metal on metal abrasion problem associated with the Product.

48. As a result of the injured Plaintiff's implantation with the defective device and resulting pain, discomfort, and other symptoms, the injured Plaintiff will likely need to undergo premature revision surgery to replace the implants.

49. The injured Plaintiff continues to experience pain and discomfort from her total hip arthroplasties.

50. All of the injuries and complications suffered by the injured Plaintiff were caused by the defective design, manufacture, marketing, sale, inadequate warnings, construction and unreasonably dangerous character of the Pinnacle Device that was implanted in the injured Plaintiff. Had Defendants not concealed the known defects, the early failure rate, the known complications and the unreasonable risks associated with the use of the Pinnacle Device, the injured Plaintiff would not have consented to the Pinnacle Device being used in the injured Plaintiff's total hip arthroplasties.

51. Prior to in and around late Fall 2010, the injured Plaintiff was unaware of any causal link between the injuries the injured Plaintiff has suffered and any wrongdoing on the part of Defendants due to the faulty and defective nature of the Pinnacle Device, due in part to the failures of Defendants to properly and adequately warn the injured Plaintiff and the injured Plaintiff's physicians about the Pinnacle Device's defective and faulty nature. The injured Plaintiff was unable to make an earlier discovery of said causal link despite reasonable diligence because of Defendants' failure to properly and adequately warn the injured Plaintiff and the injured Plaintiff's physicians about the Pinnacle Device's defective and faulty nature, and

Defendants' failure to issue any recall or take any other proactive action to date with respect to the injuries being caused to patients that have been implanted with a Pinnacle Device.

52. As a foreseeable, direct, and proximate result of the wrongful acts and omissions of defendants, the injured Plaintiff was caused to suffer economic damages, severe and possibly permanent injuries, pain, suffering, mental suffering, and emotional distress.

CAUSES OF ACTION

FIRST CAUSE OF ACTION

NEGLIGENCE

(Against All Defendants)

53. The injured Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

54. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control, and/or distribution of the Pinnacle Device into the stream of commerce, including a duty to assure that the device would not cause those who had it surgically implanted to suffer adverse harmful effects from it.

55. Defendants failed to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control, and/or distribution of the Pinnacle Device into interstate commerce in that Defendants knew or should have known that those individuals that had the device surgically implanted were at risk for suffering harmful effects from it including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are

permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

56. The negligence of Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a. Negligently designing the Pinnacle Device in a manner which was dangerous to those individuals who had the device surgically implanted;

b. Designing, manufacturing, producing, creating, and/or promoting the Pinnacle Device without adequately, sufficiently, or thoroughly testing it;

c. Not conducting sufficient testing programs to determine whether or not the aforesaid Pinnacle Device was safe for use;

d. Defendants herein knew or should have known that Pinnacle Device was unsafe and unfit for use by reason of the dangers to its users;

e. Selling the Pinnacle Device without making proper and sufficient tests to determine the dangers to its users;

f. Negligently failing to adequately and correctly warn the injured Plaintiff or their physicians, hospitals and/or healthcare providers of the dangers of Pinnacle Device;

g. Negligently failing to recall their dangerous and defective Pinnacle Device at the earliest date that it became known that the device was, in fact, dangerous and defective;

h. Failing to provide adequate instructions regarding safety precautions to be observed by surgeons who would reasonably and foreseeably come into contact with, and more particularly, implant the Pinnacle Device into their patients;

i. Negligently advertising and recommending the use of the Pinnacle Device despite the fact that Defendants knew or should have known of its dangerous propensities;

j. Negligently representing that the Pinnacle Device offered was safe for use for its intended purpose, when, in fact, it was unsafe;

k. Negligently manufacturing the Pinnacle Device in a manner which was dangerous to those individuals who had it implanted;

l. Negligently producing the Pinnacle Device in a manner which was dangerous to those individuals who had it implanted;

m. Negligently assembling the Pinnacle Device in a manner which was dangerous to those individuals who had it implanted;

n. Defendants under-reported, underestimated and downplayed the serious danger of the Pinnacle Device.

57. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of the Pinnacle Device in that they:

a. Failed to use due care in designing and manufacturing the Pinnacle Device so as to avoid the aforementioned risks to individuals that had the devices surgically implanted;

b. Failed to accompany their product with proper warnings;

c. Failed to accompany their product with proper instructions for use;

d. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the Pinnacle Device; and

e. Were otherwise careless and/or negligent.

58. Despite the fact that Defendants knew or should have known that the Pinnacle Device caused harm to individuals that had the device surgically implanted, Defendants continued to market, manufacture, distribute and/or sell the Pinnacle Device.

59. Defendants knew or should have known that consumers such as the injured Plaintiff would suffer foreseeable injury, and/or be at increased risk of suffering injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

60. Defendants' negligence was the proximate cause of the injured Plaintiff's physical, mental and emotional injuries and harm, and economic loss which the injured Plaintiff has suffered and/or will continue to suffer.

61. By reason of the foregoing, the injured Plaintiff experienced and/or will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

62. Further, as a result of the foregoing acts and omissions, the injured Plaintiff has and/or will in the future suffer a diminished earning capacity.

63. In performing the foregoing acts and omissions, Defendants acted despicably, fraudulently, and with malice and oppression so as to justify an award of punitive and exemplary damages.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY (MANUFACTURING DEFECT)

(Against All Defendants)

64. The injured Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

65. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Device.

66. The Pinnacle Device that was surgically implanted in the injured Plaintiff was defective in its manufacture when it left the hands of Defendants in that it deviated from product specifications, posing a serious risk that it could fail early in patients therefore giving rise to physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

67. As a direct and proximate result of Defendants' placement of the defective Pinnacle Device into the stream of commerce, the injured Plaintiff experienced and/or will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

68. Further, as a result of the foregoing acts and omissions, the injured Plaintiff has and/or will in the future suffer a diminished earning capacity.

69. In performing the foregoing acts and omissions, Defendants acted despicably, fraudulently, and with malice and oppression so as to justify an award of punitive and exemplary damages.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY (DESIGN DEFECT)

(Against All Defendants)

70. The injured Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

71. At all times herein mentioned, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the Pinnacle Device as hereinabove described that was surgically implanted in the injured Plaintiff.

72. At all times herein mentioned, the Pinnacle Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendants was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users such as the injured Plaintiff that had the device surgically implanted.

73. At all times herein mentioned, the Pinnacle Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendants was in an unsafe, defective, and inherently dangerous condition at the time it left Defendants' possession.

74. At all times herein mentioned, the Pinnacle Device was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without

substantial change in the condition in which it was designed, produced, manufactured, sold, distributed, and marketed by Defendants.

75. At all times herein mentioned, the Pinnacle Device's unsafe, defective, and inherently dangerous condition was a cause of injury to the injured Plaintiff.

76. At all times herein mentioned, the Pinnacle Device failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

77. The injured Plaintiff's injuries resulted from use of the Pinnacle Device that was both intended and reasonably foreseeable by Defendants.

78. At all times herein mentioned, the Pinnacle Device posed a risk of danger inherent in the design which outweighed the benefits of that design.

79. At all times herein mentioned, the Pinnacle Device was defective and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by Defendants.

80. Defendants knew, or should have known, that at all times herein mentioned that the Pinnacle Device was in a defective condition, and was and is inherently dangerous and unsafe.

81. At the time of the implantation of the Pinnacle Device into the injured Plaintiff, the aforesaid product was being used for the purposes and in a manner normally intended, namely for use as a hip replacement device.

82. Defendants, with this knowledge, voluntarily designed their Pinnacle Device in a dangerous condition for use by the public and, in particular, the injured Plaintiff.

83. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

84. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers and to the injured Plaintiff, in particular, and Defendants are therefore strictly liable for the injuries sustained by the injured Plaintiff.

85. As a direct and proximate result of Defendants' placement of the defective Pinnacle Device into the stream of commerce, the injured Plaintiff experienced and/or will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

86. Further, as a result of the foregoing acts and omissions, the injured Plaintiff has and/or will in the future suffer a diminished earning capacity.

87. In performing the foregoing acts and omissions, Defendants acted despicably, fraudulently, and with malice and oppression so as to justify an award of punitive and exemplary damages.

FOURTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY (INADEQUATE WARNING)

(Against All Defendants)

88. The injured Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

89. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Device.

90. The Pinnacle Device placed into the stream of commerce by Defendants was defective due to inadequate warning, because Defendants knew or should have known that the Pinnacle Device could fail early in patients and therefore give rise to physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery, but failed to give consumers adequate warning of such risks. These material risks were not a matter of common knowledge to persons in the same or similar position as the injured Plaintiff. Further, the Pinnacle Device placed into the stream of commerce by Defendants was surgically implanted in a manner reasonably anticipated by Defendants. Defendant knew or should have known about the risk of harm based on the scientific, technical, or medical information reasonably available at the time the specific unit of the product left the control of the manufacturer.

91. As a direct and proximate result of Defendants' placement of the defective Pinnacle Device into the stream of commerce, the injured Plaintiff experienced and/or will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

92. Further, as a result of the foregoing acts and omissions, the injured Plaintiff has and/or will in the future suffer a diminished earning capacity.

93. In performing the foregoing acts and omissions, Defendants acted despicably, fraudulently, and with malice and oppression so as to justify an award of punitive and exemplary damages.

FIFTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

(Mass. Gen. Laws Ann. Ch. 106, § 2-313)

(Against All Defendants)

94. The injured Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

95. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Device.

96. Defendants expressly warranted that the Pinnacle Device was a safe and effective hip replacement system.

97. The Pinnacle Device placed into the stream of commerce by Defendants did not conform to these express representations because they failed early thereby giving rise to unnecessary physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

98. As a direct and proximate result of Defendants' breach of express warranties regarding the safety and effectiveness of the Pinnacle Device, the injured Plaintiff experienced

and/or will experience significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty device, and will continue to suffer such damages in the future.

99. In taking the actions and omissions that caused these damages, Defendants were guilty of malice, oppression and fraud, and the injured Plaintiff is therefore entitled to recover punitive damages.

SIXTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY; USAGE OF TRADE

(Mass. Gen. Laws Ann. Ch. 106, §§ 2-314, *et seq.*)

(Against All Defendants)

100. The injured Plaintiff incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

101. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Device.

102. At the time Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Device, Defendants knew the use for which the Pinnacle Device was intended, and impliedly warranted the Pinnacle Device to be of merchantable quality and safe for such use.

103. The injured Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether the Pinnacle Device was of merchantable quality and safe for its intended use.

104. Contrary to Defendants' implied warranties, the Pinnacle Device was not of merchantable quality or safe for its intended use, because the Pinnacle Device was unreasonably

dangerous and/or not reasonably fit for its intended, anticipated or reasonably foreseeable use as described above.

105. As a direct and proximate result of Defendants' breach of implied warranties regarding the safety and effectiveness of the Pinnacle Device, the injured Plaintiff experienced and/or will experience significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty device, and will continue to suffer such damages in the future.

106. In taking the actions and omissions that caused these damages, Defendants were guilty of malice, oppression and fraud, and the injured Plaintiff is therefore entitled to recover punitive damages.

SEVENTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

(Against All Defendants)

107. The injured Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

108. The Defendants supplied false information to the public, to the injured Plaintiff and to The injured Plaintiff's physicians regarding the high-quality, safety and effectiveness of the Pinnacle Device. Defendants provided this false information to induce the public, the injured Plaintiff and the injured Plaintiff's physicians to purchase and implant a Pinnacle Device.

109. The Defendants knew or should have known that the information they supplied regarding the purported high-quality, safety and effectiveness of the implant to induce the

injured Plaintiff and The injured Plaintiff's physicians to purchase and use a Pinnacle Device was false.

110. The Defendants were negligent in obtaining or communicating false information regarding the purported high-quality, safety and effectiveness of the Pinnacle Device.

111. The injured Plaintiff and the injured Plaintiff's physicians relied on the false information supplied by the Defendants to the injured Plaintiff's detriment by causing the Pinnacle Device to be purchased and implanted in the injured Plaintiff.

112. The injured Plaintiff and the injured Plaintiff's physicians were justified in their reliance on the false information supplied by the Defendants regarding the purported high-quality, safety and effectiveness of the Pinnacle Device.

113. As a direct and proximate result of Defendants' negligent misrepresentations, the injured Plaintiff experienced and/or will experience significant damages, including but not limited to permanent physical injury, economic loss, pain and suffering and the need revision surgery to repair the physical damage to the injured Plaintiff caused by the Pinnacle Device.

EIGHTH CAUSE OF ACTION

FRAUD

(Against All Defendants)

114. The injured Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

115. Defendants made representations to the injured Plaintiff and the injured Plaintiff's physicians that their Pinnacle Device is a high-quality, safe and effective hip replacement system.

116. Before they marketed the Pinnacle Device that was implanted in the injured Plaintiff, Defendants knew or should have known of the unreasonable dangers and serious health risks that such a metal-on-metal total hip replacement system posed to patients like the injured Plaintiff.

117. As specifically described in detail above, Defendants knew that the Pinnacle Device subjected patients to early failure, painful and harmful physical reactions to toxic metallic particles and ions, death of tissue, bone loss and the need for explants and revision surgery.

118. Defendants' representations to the injured Plaintiff and The injured Plaintiff's physicians that their Pinnacle Device is high-quality, safe and effective were false.

119. Defendants concealed their knowledge of the unreasonable risks and dangers associated with the use of the Pinnacle Device to induce the injured Plaintiff and many thousands of others to purchase the system for surgical implantation in their bodies.

120. Neither the injured Plaintiff nor the injured Plaintiff's physicians knew of the falsity of Defendants' statements regarding the Pinnacle Device.

121. The injured Plaintiff and the injured Plaintiff's physicians relied upon and accepted as truthful Defendants' representations regarding the Pinnacle Device.

122. The injured Plaintiff and the injured Plaintiff's physicians had a right to rely on Defendants' representations and in fact did rely upon such representations. Had the injured Plaintiff known that the Pinnacle Device would fail early and expose the injured Plaintiff to the unreasonable risk of toxic metals, metallosis, and multiple revision surgeries the injured Plaintiff would not have purchased or allowed the Pinnacle Device to have been surgically implanted.

123. As a direct and proximate result of Defendants' fraudulent representations, the injured Plaintiff has experienced and/or will experience significant damages, including but not limited to permanent physical injury, economic loss, pain and suffering and the need revision surgery to repair the physical damage to the injured Plaintiff caused by the Pinnacle Device.

NINTH CAUSE OF ACTION

VIOLATION OF CONSUMER PROTECTION LAWS

(Mass. Gen. Laws Ann. Ch. 93A *et seq*.)

(Against All Defendants)

124. The injured Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

125. Defendants unfairly, unconscionably, and deceptively advertised, marketed, sold, and represented the Pinnacle Device as a high-quality, safe and effective hip replacement system to the injured Plaintiff and the injured Plaintiff's physicians.

126. Before they advertised, marketed, sold and represented the Pinnacle Device that was implanted in the injured Plaintiff, Defendants knew or should have known of the unreasonable dangers and serious health risks that such a metal-on-metal total hip replacement system posed to patients like the injured Plaintiff.

127. The injured Plaintiff purchased and used the Pinnacle device for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

128. Had Defendants not engaged in the deceptive conduct described herein, the injured Plaintiff would not have purchased and/or paid for the Pinnacle device, and would not have incurred related medical costs and injury.

129. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from the injured Plaintiff for the Pinnacle device that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

130. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a. Representing that goods or services have characteristics, ingredients, uses, benefits or quantities that they do not have;

b. Advertising goods or services with the intent not to sell them as advertised; and,

c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

131. The injured Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Pinnacle device. Each aspect of Defendants' conduct combined to artificially create sales of the Pinnacle device.

132. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and sale of the Pinnacle device.

133. Had Defendants not engaged in the deceptive conduct described above, the injured Plaintiff would not have purchased and/or paid for the Pinnacle device, and would not have incurred related medical costs.

134. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including the injured Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

135. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes.

136. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of Mass. Gen. Laws Ann. Ch. 93A *et seq*.

137. Under the statute listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

138. Defendants violated the statutes that were enacted in this state to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Pinnacle device was fit to be used for the purpose for which it was intended, when in fact the device was defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials.

139. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

140. Defendants had actual knowledge of the defective and dangerous condition of the Pinnacle device and failed to take any action to cure such defective and dangerous conditions.

141. The injured Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which hip implant device to use and recommend.

142. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

143. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, the injured Plaintiff has suffered ascertainable losses and damages.

144. As a direct and proximate result of Defendants' violations of the states' consumer protection laws, the injured Plaintiff has sustained economic losses and other damages and is entitled to statutory and compensatory, damages in an amount to be proven at trial.

145. As specifically described in detail above, Defendants knew that the Pinnacle Device subjected patients to early failure, painful and harmful physical reactions to toxic metallic particles and ions, death of tissue, bone loss and the need for explants and revision surgery.

146. As a direct and proximate result of Defendants' representations, the injured Plaintiff has experienced and/or will experience significant damages, including but not limited to permanent physical injury, economic loss, pain and suffering and the need revision surgery to repair the physical damage to the injured Plaintiff caused by the Pinnacle Device

TENTH CAUSE OF ACTION

PUNITIVE DAMAGES

(Against All Defendants)

147. The injured Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

148. The acts and/or omissions of Defendants as set forth supra, were knowing and willful failures to warn of the failures of the product and lack of efficacy and risks, and they constituted malicious, willful, wanton, and/or reckless conduct.

149. The Defendants knew or should have known that its product failed at a high rate. Nevertheless, they continued to market the product by providing false and misleading information with regard to safety and efficacy.

150. At all times relevant herein, Defendants:

(a) Knew that the product was dangerous;

(b) Concealed the dangers and health risks from the injured Plaintiff, her physicians and the public at large;

(c) Made misrepresentations to the injured Plaintiff, her physicians and the public in general as previously delineated herein as to the safety and efficacy of the product;

(d) Failed to inform and misled the FDA as to the failure rate and dangers of the product;

151. Defendants' acts were willful, wanton and malicious, and showed a total disregard for human life and human suffering. Based upon the acts alleged herein, Defendants knew or should have known, that the very patients whose lives were supposed to be improved by the hip implants, would instead be subject to enhanced pain and suffering and duplicative

and unnecessary surgeries, that their conduct would naturally and probably result in injury and damage. Defendants continued such conduct with malice and/or in reckless disregard of the consequences, from which malice may be inferred. The injured Plaintiffs should be awarded punitive damages against Defendants, based upon the acts herein so as to punish Defendants and deter similar conduct by Defendants.

WHEREFORE, the injured Plaintiff demands judgment against the defendants, and each of them, individually, jointly and severally and requests compensatory damages in a sum in excess of $75,000, together with punitive damages, interest, attorneys fees, cost of suit, and all such other relief as the Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, the injured Plaintiff prays for the following relief:

A. Judgment in favor of the injured Plaintiff and against all Defendants, for damages in such amounts as may be proven at trial;

B. Compensation for both economic and non-economic losses, including but not limited to medical expenses, disfigurement, pain and suffering, mental anguish and emotional distress, in such amounts as may be proven at trial;

C. Punitive and/or exemplary damages in such amounts as may be proven at trial;

D. Attorneys' fees and costs;

E. Pre- and post-judgment interest; and

F. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

Dated: September 6, 2012

Respectfully Submitted,

Weitz & Luxenberg, P.C.
Attorneys for the injured Plaintiff

By: /s/ Peter Samberg
Peter Samberg

700 Broadway,
New York, NY 10003

DEMAND FOR JURY TRIAL

The injured Plaintiff JUDITH M. SPARANGES hereby demands a trial by jury.

Dated: September 6, 2012

Respectfully Submitted,

Weitz & Luxenberg, P.C.
Attorneys for the injured Plaintiff

By: /s/ Peter Samberg
Peter Samberg

700 Broadway,
New York, NY 10003